IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA

HIGHMARK INC., and KEYSTONE HEALTH PLAN WEST, INC., Plaintiffs,	:	Case No. _____
vs.	:	
MICHAEL F. CONSEDINE, Commissioner, Pennsylvania Insurance Department,	:	
KATHLEEN G. KANE, Attorney General, Commonwealth of Pennsylvania, and	:	
MICHAEL E. WOLF, Secretary, Pennsylvania Department of Health, Defendants.	:	

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs, Highmark Inc. and Keystone Health Plan West, Inc. ("KHPW" and collectively with Highmark Inc., "Highmark"), by their undersigned attorneys, state as follows for their Complaint for Declaratory and Injunctive Relief against Defendants Michael F. Consedine, Kathleen G. Kane, and Michael E. Wolf:

NATURE OF ACTION

1. Highmark is offering Western Pennsylvania seniors a new Medicare Advantage ("MA") product for the 2015 enrollment year called Community Blue Medicare HMO ("Community Blue MA"). Open enrollment for Community Blue MA begins on October 15, 2014, and Highmark's marketing of the product has already begun.

2. Community Blue MA is a limited network product that Highmark has developed to provide seniors with an additional Medicare alternative that offers access to high quality health care at a lower cost than Highmark's broad network products.

3. Highmark is offering Community Blue MA in addition to two other types of MA products – Security Blue and Freedom Blue – which provide broader network access but at higher out-of-pocket cost to members.

4. Community Blue MA, like all other Medicare products, is regulated by the federal government, specifically the Centers for Medicare and Medicaid Services ("CMS").

5. Prior to launching Community Blue MA, Highmark submitted detailed information to CMS, including information about the plan's provider network and the materials that would be used to market the product.

6. CMS approved Community Blue MA and its marketing materials, having determined that Community Blue MA complied with all applicable federal regulations.

7. On October 10, 2014, Defendants, the Attorney General of the Commonwealth of Pennsylvania, the Commissioner of Insurance and the Secretary of Health, filed an Application in the Commonwealth Court of Pennsylvania against Highmark (the "Application") claiming that Highmark's rollout of Community Blue MA violates the Consent Decrees entered by the Commonwealth Court on or about July 1, 2014, one of which applies to Highmark (the "Consent Decree"). In their enforcement action, Defendants seek to require Highmark or KHPW to, *inter alia*:

- "expand its [federally-approved] provider network for any Medicare Advantage Plan it offers in Western Pennsylvania to include UPMC physicians, facilities and services, for the [5 year] duration of the Consent Decree";

- "refrain from restricting its Community Blue [MA] members from using UPMC";
- "reimburse any members of its Medicare Advantage plans who is charged by UPMC on an out-of-network basis after January 1, 2015 for the [five year] duration of the Consent Decree";
- and be enjoined "from the promotion, marketing or sale of any Limited Network Medicare Advantage Product that excludes UPMC physicians, facilities and services" (collectively referred to herein as "Defendants' Requested Enforcement Relief").

A copy of the Defendants' Application is attached hereto as **Exhibit A**.

8. Also on October 10, 2014, the Pennsylvania Insurance Department Executive Offices, upon information and belief at the direction of Defendant Consedine or others acting at his direction, issued a Notice to Western Pennsylvania insurance brokers (the "Notice"), stating that:

> [A]t this point, Community Blue Medicare Advantage – the Medicare Advantage product recently announced by Highmark, which denies its subscribers In-Network access to UPMC facilities and providers – may not be compliant with the Consent Decree and is currently the subject of legal review in Commonwealth Court. Therefore producers offering this product, which may be inconsistent with the Consent Decree, may run the risk of violating Pennsylvania's Unfair Insurance Practices Act (40 P.S. §§ 1171.1) et seq., and its prohibition of making false or fraudulent statements, or misrepresentations in the context of the sale of an insurance product.

A copy of the Notice is attached hereto as **Exhibit B.**

9. Defendants' actions and Defendants' Requested Enforcement Relief – in addition to being anti-competitive and harmful to Western Pennsylvania seniors – are preempted by federal law and conflict with both the procedural and substantive requirements that Congress has established for the development, marketing and sale of all Medicare products, including Community Blue MA.

10. The MA statute is explicit that it, and the implementing regulations adopted thereunder, "**shall supersede any State law or regulation** (other than State licensing laws or

State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part." 42 U.S.C. § 1395w-26(b)(3) (2006)(emphasis added).

11. Defendants cannot lawfully impose on Highmark requirements for Community Blue MA different than or additional to those imposed by the federal government and similarly cannot lawfully attempt to prevent the marketing and sale of an MA plan that the federal government has expressly approved.

12. For that reason, Highmark respectfully requests that this Court issue a declaratory judgment pursuant to 28 U.S.C. § 2201 that Defendants' actions are preempted by federal law and further requests that this Court enjoin Defendants pursuant to Fed. R. Civ. P. 65 from any and all actions to obtain Defendants' Requested Enforcement Relief.

JURISDICTION AND VENUE

13. Jurisdiction is premised on 28 U.S.C. § 1331, this being a civil action arising under the Constitution and laws of the United States.

14. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events giving rise to Highmark's claims occurred in this judicial district.

THE PARTIES

15. Plaintiff Highmark Inc. is a health insurer and Pennsylvania nonprofit corporation with its principal place of business in Pittsburgh, Pennsylvania. Highmark does business in the 29 counties of western Pennsylvania as Highmark Blue Cross Blue Shield, an independent licensee of the Blue Cross Blue Shield Association.

16. Plaintiff Keystone Health Plan West, Inc. is a health maintenance organization and subsidiary of Highmark. KHPW is a nonprofit corporation with its principal place of business in Pittsburgh, Pennsylvania.

17. Defendant Michael F. Consedine is the Insurance Commissioner of the Commonwealth of Pennsylvania with a principal place of business at 1326 Strawberry Square, Harrisburg, Pennsylvania 17120.

18. Defendant Kathleen G. Kane is the Attorney General of the Commonwealth of Pennsylvania with a principal place of business at Strawberry Square, 16th Floor, Harrisburg, Pennsylvania 17120.

19. Defendant Michael E. Wolf is the Secretary of the Pennsylvania Department of Health with a principal place of business at Health and Welfare Building, 8th Floor West, 625 Forster Street , Harrisburg, Pennsylvania 17120.

FACTUAL BACKGROUND

I. Federal Regulation of Medicare Advantage Products

20. The Medicare Act, enacted as Title XVIII of the Social Security Act and codified at 42 U.S.C. §§ 1395–1395kkk (2012), creates a federally subsidized nationwide health insurance program for elderly and disabled individuals. Pursuant to Part C of the Act, beneficiaries may receive Medicare benefits through MA plans provided by private entities called MA organizations. 42 C.F.R. § 422.2 (2010).

21. KHPW is a contracted MA plan.

22. MA products, including Highmark's Community Blue MA, are subject to extensive regulation by CMS. The regulations contained in 42 C.F.R. § 422 *et seq.* govern the requirements and standards for MA products, including issues of provider selection, network adequacy, and quality assurance, as well as review and approval of marketing materials.

23. As explained further below, Community Blue MA has been approved by CMS because it meets all of the federally-mandated regulatory requirements.

A. Community Blue MA Complies With Federal Network-Related Regulations and Was Approved by CMS.

24. Community Blue MA is a "coordinated care plan," which is defined as "a plan that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by CMS." 42 C.F.R. § 422.2(a)(1). As such, "[t]he network" must be "approved by CMS to ensure that all applicable requirements are met, including access and availability, service area, and quality." 42 C.F.R. § 422.2(a)(1)(i).

25. The regulations further provide that "[a]n MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan." 42 C.F.R. § 422.112(a). To do so, the MA organization must, among other things, "[m]aintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served." 42 C.F.R. § 422.112(a)(1)(i).

26. As part of Highmark's Community Blue MA plan description, Highmark was required by CMS to include information about the "number, mix and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services; [and] any out of network coverage[.]" 42 C.F.R. § 422.111(b)(3)(i).

27. In accordance with the applicable regulatory requirements, in early June 2014, Highmark submitted to CMS its proposed plan designs for each of its MA products, including Community Blue MA, which included the benefit package and rate filing for Community Blue MA.

28. Highmark also provided CMS, in early June 2014, detailed information about the providers that would be included in the network for Community Blue MA.

29. Pursuant to its regulations, CMS evaluates proposed provider networks to ensure that, among other things, they meet Medicare access and availability requirements in a manner "consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered." 42 C.F.R. § 422.112(a)(10). CMS uses several factors in making this evaluation, including but not limited to:

> (i) The number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans.
>
> (ii) The prevailing market conditions in the service area of the MA plan. Specifically, the number and distribution of health care providers contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan.
>
> (iii) Whether the service area is comprised of rural or urban areas or some combination of the two.
>
> (iv) Whether the MA plan's proposed provider network meets Medicare time and distance standards for member access to health care providers including specialties.
>
> (v) Other factors that CMS determines are relevant in setting a standard for an acceptable health care delivery network in a particular service area.

Id.

30. CMS reviewed the Community Blue MA information submitted by Highmark to determine whether Community Blue MA complies with the above-referenced regulations.

31. Community Blue MA's limited network – which allows Highmark to offer the product to subscribers at a lower cost than its broad network plans – is consistent with Medicare regulations, which specifically permit MA organizations to "offer multiple plans," 42 C.F.R. §

422.4(b), and to implement "measures designed to maintain quality and control costs consistent with its responsibilities." 42 C.F.R. § 422.205(b)(3).

32. Before and throughout the review process, Highmark representatives had multiple communications with CMS regulators, explaining the Community Blue MA product and detailing the fact that Community Blue MA has a limited network.

33. Highmark representatives specifically discussed with CMS regulators that, although UPMC had been offered participation in the Community Blue MA network, UPMC declined and UPMC doctors and hospitals, as well as several other area providers, would not be included in Community Blue MA network.

34. CMS approved Community Blue MA on or about August 18, 2014, following these discussions, and after full disclosure by Highmark of the details of the product's provider network.

B. Community Blue MA Marketing Materials Comply with Federal Regulations and Were Approved by CMS.

35. Defendants, in their Application to the Commonwealth Court, contend that Highmark's marketing of Community Blue MA violates Section IVA(11) of the Consent Decree.

36. Highmark developed and submitted to CMS for review and approval the materials that would be used to market the product.

37. The federal regulations contained in 42 C.F.R. § 422 *et seq.* provide for extensive regulation and review by CMS of marketing materials for MA plans.

38. "Marketing materials" are broadly defined as including "any informational materials targeted to Medicare beneficiaries which," *inter alia*, "[p]romote the MA organization, or any MA plan offered by the MA organization" or "[e]xplain the benefits of enrollment in an MA plan[.]" 42 C.F.R. § 422.2260.

39. "Marketing materials" specifically include, *inter alia*, general circulation brochures, newspapers, magazines, television, radio, billboards, Internet, scripts or outlines for telemarketing, subscriber agreements, member handbooks and wallet card instructions. *Id.*

40. Federal regulations provide that an MA organization may not distribute marketing materials or election/enrollment forms unless it first submits them to CMS for review "[a]t least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language and format, including standardized language and formatting, as specified by CMS) before the date of distribution" and CMS does not disapprove. 42 C.F.R. § 422.2262(a)(1).

41. In the late Summer of 2014, Highmark submitted its marketing materials related to Community Blue MA to CMS on a rolling basis in accordance with § 422.2262.[1]

42. CMS reviews marketing materials to ensure that, *inter alia*, they provide adequate information to Medicare beneficiaries interested in enrolling, including "[a]dequate written description of rules (**including any limitations on the providers from whom services can be obtained**), procedures, basic benefits and services, and fees and other charges" and "[a]ny other information necessary to enable beneficiaries to make an informed decision about enrollment." 42 C.F.R. § 422.2264(a) (emphasis added).

43. CMS also reviews marketing materials to ensure that they "are not materially inaccurate or misleading or [do not] otherwise make material misrepresentations." 42 C.F.R. § 422.2264(d).

[1] Pursuant to 42 C.F.R. § 422.2262(b), Highmark submitted a limited amount of Community Blue MA marketing material under CMS's "file and use" procedure whereby an MA organization may distribute certain types of marketing materials 5 days following their submission to CMS.

44. CMS reviewed the Community Blue MA marketing materials submitted by Highmark in the late Summer and early Fall of 2014.

45. During its review, and recognizing that Community Blue MA was a limited network product, CMS regulators reached out to Highmark to require that Highmark include a disclaimer on its Community Blue MA materials clearly indicating to subscribers that the product was a limited network product.

46. Highmark complied by including the following language in the Community Blue MA marketing materials, which was specifically approved by CMS:

> **Not all providers will accept Community Blue Medicare HMO. Please verify that your providers are participating before enrolling. If a provider does not participate, neither Medicare nor Community Blue Medicare HMO will be responsible for the costs.**

47. Following inclusion by Highmark of the above disclaimer, CMS approved the Community Blue MA marketing materials on a rolling basis on July 24, August 5, August 15, August 18, August 26, August 28, August 29, September 3, September 4, September 5, September 11 and September 22.

II. Defendants' Enforcement Action is Preempted by Federal Law

48. On or about October 10, 2014, Defendants filed the Application in the Commonwealth Court of Pennsylvania, wherein Defendants allege that Community Blue MA and the marketing materials produced in connection therewith, violates the Consent Decree. Defendants seek to require Highmark or KHPW to, *inter alia*:

- "expand its [federally-approved] provider network for any Medicare Advantage Plan it offers in Western Pennsylvania to include UPMC physicians, facilities and services, for the [5 year] duration of the Consent Decree";

- "refrain from restricting its Community Blue [MA] members from using UPMC";
- "reimburse any members of its Medicare Advantage plans who is charged by UPMC on an out-of-network basis after January 1, 2015 for the [five year] duration of the Consent Decree";
- and be enjoined "from the promotion, marketing or sale of any Limited Network Medicare Advantage Product that excludes UPMC physicians, facilities and services" (collectively referred to herein as "Defendants' Requested Enforcement Relief").

See Exhibit A.

49. Specifically, Defendants interpret the Consent Decree to require that Highmark, among other things, "expand its [federally-approved] provider network for any Medicare Advantage Plan it offers in Western Pennsylvania to include UPMC physicians, facilities and services, for the **[5 year]** duration of the Consent Decree". *Id.*

50. Defendants also informed Western Pennsylvania insurance brokers that they "run the risk of violating the Pennsylvania Insurance Practices Act in (40 P.S. §§ 1171.1) et seq." if they continue to offer Community Blue MA to subscribers. *See* Exhibit B.

51. The Consent Decree does not require that Highmark include certain UPMC hospitals and doctors as "in network" for all Highmark products, including Community Blue MA.

52. This Court need not reach the substance of Defendants' state law claims, however, because Defendants' interpretation of the Consent Decree and Defendants' Requested Enforcement Relief are preempted by federal law.

COUNT I
(Highmark v. All Defendants)
Declaratory Judgment Pursuant to 28 U.S.C. § 2201

53. Highmark incorporates herein by reference as if set forth in full paragraphs 1-49 hereof.

54. Defendants, through their Application seeking relief from the Commonwealth Court of Pennsylvania in the nature of an order requiring Highmark to alter or shut down entirely its Community Blue MA product, seek to impose state regulations and requirements on Highmark's MA product.

55. Defendants' enforcement action violates the Supremacy Clause of the United States Constitution, Article VI § 2, in that it conflicts with paramount federal law, namely 42 U.S.C. § 1395w-26(b)(3), which provides for federal preemption of state laws and regulations with respect to MA plans, and 42 C.F.R. § 422 *et seq*., the federal regulations governing, *inter alia*, the provider network and marketing for MA plans.

56. Congress has clearly expressed its intent that federal statutes and regulations regarding Medicare, including those related to provider networks and marketing materials, shall preempt state law. The Medicare Part C statute governing MA plans contains an express preemption clause which provides:

> The standards established under this part **shall supersede any State law or regulation** (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.

42 U.S.C. § 1395w-26(b)(3) (2006) (emphasis added).

57. CMS's interpretation of the federal regulations of MA confirms the broad scope of federal preemption:

> **The scope of Federal preemption is broad.**
>
> […]
>
> "**All State standards, including those established through case law, are preempted to the extent that they would specifically regulate health plans (including MA plans), with the exceptions of State licensing and solvency laws**."

Medicare Managed Care Manual, Chapter 10, § 30.1-30.2 (Rev. 103, Nov. 4, 2011) (emphasis added).

58. CMS has further stated that "States may not review or impose State standards for network or organizational capacity." *Id.* at § 60.

59. Defendants' enforcement action plainly conflicts with and is preempted by federal law, specifically the federal regulations detailed herein.

PRAYER FOR RELIEF

WHEREFORE, Highmark prays that the Court enter:

1. A declaratory judgment pursuant to 28 U.S.C. § 2201 that Defendants' enforcement action against Highmark, seeking Defendants' Requested Enforcement Relief, including to require Highmark or KHPW to add additional providers to the federally-approved provider network and to alter the federally-approved marketing materials for Community Blue MA and to enjoin or prohibit Highmark or KHPW from marketing or selling Community Blue MA, is preempted by federal law and is unconstitutional;

2. An order enjoining Defendants from any and all actions seeking Defendants' Requested Enforcement Relief, including to require Highmark or KHPW to add additional providers to the federally-approved provider network and to alter the

federally-approved marketing materials for Community Blue MA and to enjoin or prohibit Highmark from marketing or selling Community Blue MA; and

3. Such other and further relief as is authorized by law or as may be deemed necessary and proper.

Respectfully submitted,

By: REED SMITH LLP

By: /s P. Gavin Eastgate

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